

**UNITED STATES DISTRICT COURT  
NORTHERN DISTRICT OF OKLAHOMA**

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Case No. 20-CR-004-GKF
	)	
ELISA KAYE SANDERS,	)	
	)	
Defendant.	)	

**DEFENDANT’S RESPONSE TO GOVERNMENT’S  
AMENDED SENTENCING MEMORANDUM (DKT. #108)**

COMES NOW the Defendant, Elisa Kaye Sanders, by and through her attorneys of record, Mark D. Lyons and Martha L. Blackburn of Lyons & Clark, Inc., and for her Response to the Government’s Amended Sentencing Memorandum (Dkt. #108) hereby states as follows:

In its Amended Sentencing Memorandum, the Government admits Ms. Sanders should receive full probation when sentenced for the *misdemeanor offense* of receipt of a misbranded drug in interstate commerce. The factual basis for this charge is she received Botox from Canada. This Court likely well knows the publicity and political issue in the last number of years of the high cost of drugs in the United States while pharmacies (and/or drug companies) in Canada sell the exact same drugs at much lower costs. In 2019, the Washington Post reported on a caravan of Americans that went to Canada to buy a supply of insulin for \$1,200.00 that would have cost **\$12,000.00** in the United States.<sup>1</sup> If that happened in this case, the FDA Special Agents and Government lawyers would argue the mere purchase of drugs through a Canadian supplier meant the drugs were misbranded. As that phrase is used, it means the “labels” and “labeling” (which are statutorily

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<sup>1</sup>[https://www.washingtonpost.com/world/the\\_americas/as-price-of-insulin-soars-americans-caravan-to-canada-for-lifesaving-medicine/2019/06/14/0a272fb6-8217-11e9-9a67-a687ca99fb3d\\_story.html](https://www.washingtonpost.com/world/the_americas/as-price-of-insulin-soars-americans-caravan-to-canada-for-lifesaving-medicine/2019/06/14/0a272fb6-8217-11e9-9a67-a687ca99fb3d_story.html)

defined terms) were not approved by the FDA. Therefore the drugs would be contraband and various crimes would have been committed. No one in the caravan was arrested, charged or prosecuted.

Attached hereto as Exh. 1 are advertisements from the Tulsa World where Canadian pharmacies are openly advertising the sale of drugs.

Market Watch published an article on May 29<sup>th</sup>, 2021 about how big pharmaceutical companies have raised the costs of 800 different drugs during the pandemic to earn higher profits.<sup>2</sup>

Attached hereto as Exh. 2 is an article about an extensive Reuters investigation of how FDA criminal investigators have been “co-opted” by Allergan U.S.A. to prosecute the purchase of Botox from Canada while ignoring more pressing investigations. The article reads in part, “Some FDA agents complain they have been turned into the “Botox Police” - chasing down every doctor who purchases the authentic version of the popular anti-wrinkle drug that were labeled for use in other countries, an exercise producing few results.” The agents have also coined another phrase referring to themselves as the “ATF”, “Allergan Task Force”. The article reports that 53% of all Botox investigations were closed without action.

Another news article noted that there was such a Congressional outcry over the diversion of FDA resources to investigate the purchase of Botox from sources other than Allergan, that the director of FDA Criminal Investigations, George Karavestos, was forced to step down. See Exh. 3. This was in part because so many federal prosecutors declined to file any charges for foreign Botox purchases as the cases lacked prosecutive merit.

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<https://www.marketwatch.com/story/empowering-medicare-to-negotiate-cheaper-drug-prices-could-finally-break-big-pharmas-grip-on-our-health-11622095288>

In 2019, two of Allergan's cosmetic drugs Botox and Juvederm, accounted for \$5.03 Billion of the company's total \$16.9 Billion in sales.<sup>3</sup> These drugs derive so much money for Allergan as virtually all the Botox sales, and all of Juvederm sales, are for cosmetic use. Health insurance does not pay for the cosmetic uses of drugs. So it is all cash. Without price controls on drugs in the United States, Allergan can charge whatever it wants and its profits are huge.

Allergan has co-opted the FDA to prosecute the purchase of Botox from Canada because Botox from Canada, with price controls on drugs, is cheaper than Botox purchased in the U.S. Buying Botox from Canada cuts into Allergan's profits. Plain and simple. Allergan is the only company that manufactures Botox in one facility in Ireland. There is no claim here the Botox Ms. Sanders used was counterfeit or adulterated. The only claim is that it was purchased in Canada rather than from Allergan U.S.A.

As a result of the FDA's search of her medical spa, it culled through 12,000 + patient files to seize 5,000 +. This had a huge negative impact on her business which directly caused it to close and go out of business, even though the largest part of her business had nothing to do with Botox.

#### **BRIEF OVERVIEW OF THE INSTANT CASE**

As this Court likely recalls, the purchase and/or receipt of misbranded drugs in interstate commerce is simply a misdemeanor. See Title 21 U.S.C. §331. The punishment is prescribed in §333(a)(1). Importantly, the purchase and/or receipt of misbranded drugs in interstate commerce can be elevated to a felony *if* it can be proven a person "commits such a violation with the intent to

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<https://www.fiercepharma.com/special-report/allergan-top-20-pharma-companies-by-2019-revenue>

defraud or mislead”. If so, the crime is a felony with the punishment capped at up to three years and a fine of up to \$10,000.00. See §333(a)(2).

Instead of the Government charging Ms. Sanders with this crime, they instead filed two counts of mail fraud and thirteen counts of wire fraud claiming she defrauded her customers by not telling them her nursing license had been revoked; because there was improper physician supervision of the spa according to State guidelines; and that she used “unauthorized” sources of Botox; and the customers paid for spa services with debit or credit cards. Four of the wire fraud counts claim she defrauded someone (the victims were never described) by having someone buy the Botox for her. The harm to or victimization of a particular person was never made clear.

First, the Government never had evidence of the vials, the boxes nor labeling for the exact Botox administered to the claimed victims so there was no way the Government could prove exactly the labels were not FDA approved. This would be important because the Government in this case, and the Dr. Gregory Connor Botox case (*United States v. Gregory Connor*, 19-CR-58-JED), have argued that all Botox shipped from Canada did not have FDA approved labels. So historically the Government has simply claimed shipping invoices showing Botox coming from Canada was proof in and of itself the labels and labeling were not FDA approved. Yet in Dr. Connor’s case, it was proven by a purchase order married up to a shipping label, and the actual vial of Botox produced in court, that his last Botox order from Canada was made for the U.S. market because it had an FDA approved label and an FDA approved box. Boy did the Government and the FDA criminal agents have egg on their faces when their blatant misrepresentations were proven. Dr. Connor was acquitted.

Secondly, as noted in an earlier brief, for Counts 3-8, Ms. Sanders was licensed during the time period the Government alleged for this fraud.

Third, whether or not Ms. Sanders had her nursing license suspended has nothing to do with whether she can administer Botox under the supervision of a physician. The Oklahoma State Board of Medical Licensure and Supervision rules allow for a non-licensed person to administer Botox under the supervision of a physician. See the argument in Dkt. #17, at 11 and Dkt. #17-2 for the actual regulation. So the claim she defrauded her clients by not telling them her RN license was suspended was a non-issue for the purpose of charging fraud. No one ever asks a person at a spa what kind of license they have. The Government however claimed that if a person is trained to inject Botox, but isn't licensed as an RN, as a matter of fact and law they have been defrauded?

So the Government tried to make a lizard into an alligator by juicing up irrelevant facts to charge Ms. Sanders with wire fraud and mail fraud which carry a maximum of 20 years, instead of the 3 years for misbranded drug fraud. And the Government did this at the bidding of Allergan to teach Ms. Sanders a lesson and to make a point to everyone else who doesn't pay Allergan's inflated U.S. Botox prices. If you don't buy from Allergan, it will get FDA criminal agents to raid your business, get the Government to charge you with trumped up mail fraud and wire fraud charges, and shut down your business. And that's exactly what happened in this case.

This conclusion is not just speculation. The most obvious proof that Allergan got to the FDA criminal investigators is proven by the fact that the only files the Government searched for possible criminal activity, out of the 5,000 + seized, was specifically and intentionally limited to patients that received Botox and Juvederm! This testimony came out in a motion hearing on June 9<sup>th</sup>, 2020. Yet for all the other who knows how many hundreds or thousands of patients Ms. Sanders treated and

injected with drugs, without disclosing her suspended RN license, why weren't these people also defrauded? The Government didn't even make a pretense of claiming Ms. Sanders was harming the general public for all other drugs the patients received. Only Allergan products of Botox and Juvederm were targeted in the execution of the search warrant.

Of the eight counts of fraud (3-10) regarding Botox and Juvederm, with different "victims" alleged for each count, only one ever initially complained. The only complaints out of the group of 5,000 seized Botox and Juvederm patient files came after the FDA Criminal Investigators sent out letters asking for complaints. For the one person that complained independent of the FDA letters, she filed a negligence lawsuit and the matter was settled.

#### **VICTIM'S IMPACT**

The Government wants to present witnesses to testify to inconsequential facts, or their subjective conclusions, for what purpose? The Government claims Ms. Sanders should have 5 years of supervised release because she ignored Government warnings not to use Canadian sourced drugs.

The Government claims A.H. will testify Ms. Sanders violated her trust and she suffered headaches from Botox. If A.H. received Botox for headaches, then how can she isolate the cause of her headaches to what Ms. Sanders did. And if she didn't received Botox for headaches, a lay person is not qualified to testify Botox injections caused her headaches. Ms. Sanders was properly trained to and could administer Botox and Juvederm according to the regulations of the Oklahoma State Board of Medical Licensure and Supervision. So what's the point of this testimony?

The Government claims J.D. will testify that subjectively, she didn't think the Botox injections for headaches she received from Ms. Sanders lasted as long as other places she's received Botox. How is her subjective belief relevant to the punishment for Ms. Sanders?

And for the Government to allege the products at the spa were not FDA approved is not accurate. Botox is an Allergan manufactured product approved for use and distribution across the world. The use of Botox is approved for certain conditions because it is “safe and effective” and its “benefits outweigh the risks”. The FDA does not approve any drugs! It only approves the use of a drug for the treatment of certain diseases or illnesses if the rights conditions are met.

The Government wants A.P. to testify that after she learned about the “illegal products”, she felt deceived and her trust is broken. Ms. Sanders never touted God to make sales, though she is very religious. But if she did, what does that have to do with a misbranded drug or that justifies 5 years’ supervision by the probation office? That is shoving a square peg into a round hole solution.

The other witnesses the Government wants to offer also want to vent about their trust being violated; to say that Ms. Sanders is unethical; and the last one wants to bring up matters in an already resolved civil suit for which she has been paid. Out of the 12,000 spa patient files the Government found, and the 5,000 files they searched, only one person sued over a bad outcome? How does that justify spending more Government resources to supervise a 63 year old woman whose never been in trouble with the law before?

### CONCLUSION

Whether or not the Government would have won this case at trial or lost another one like it did in the Dr. Greg Connor case, the point remains this case has been compromised to a plea to one misdemeanor charge. The Government admits that probation is appropriate and does not oppose this Court sentencing Ms. Sanders to probation.

With all the other important felonies flooding this Court because of the *McGirt* decision and the time this Court should be devoting to much more serious cases than this misdemeanor, it is like

the Government still has to show Allergan it will continue to prosecute doctors or spa owners over Canadian Botox. The full perspective of this case is the Government closed down Ms. Sanders' spa business. She had to hire counsel to represent her. Isn't that punishment enough? Supervised probation for 5 years will accomplish nothing.

For the reasons stated above, the Defendant requests this Court order a minimal amount of supervision and otherwise grant her probation.

Respectfully submitted,

/s/ Mark D. Lyons  
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**CERTIFICATE OF SERVICE**

I hereby certify that on the 23<sup>rd</sup> day of September, 2021, I electronically submitted the foregoing *Defendant's Response to Amended Sentencing Memorandum (Dkt. #108)* to the Clerk of Court using the ECF System for filing and transmittal of a Notice of Electronic Filing to the following ECF registrants:

Ms. Shannon Bears Cozzoni  
Ms. Reagan Vincent Reininger  
Mr. Michael Scott Proctor

s/ Mark D. Lyons

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